Ī	SOP No.: PDP-DATA-08	Page 1 of 8				
Title: Data Storage, Retrieval, and Archival						
Ĭ	Revision: 3	Replaces: 04/01/08	Effective: 07/01/08			

1. Purpose:

To provide standard procedures for data storage, retrieval, and archival for laboratories participating in the USDA/AMS Pesticide Data Program (PDP).

2. <u>Scope</u>:

This standard operating procedure (SOP) shall be followed by all analytical laboratories conducting residue studies for PDP including support laboratories conducting stability or other types of studies that may impact the program.

3. Outline of Procedure:

- 5.1 Data Storage
- 5.2 Data and Records Retention Periods
- 5.3 Data Archival at the Participating Laboratory
- 5.4 Transferring Records to the Federal Records Centers
 - Attachment 1 PDP Designated Federal Records Centers
 - Attachment 2 Standard Form (SF)-135 Template
 - Attachment 3 Example SF-135 for Routine Data Packages
 - Attachment 4 Example SF-135 for Method Validation Data Packages
 - Attachment 5 Example SF-135 for Supporting Documentation
 - Attachment 6 Instructions for Assembly and Packaging of Record Boxes

4. <u>References</u>:

- USDA/AMS PDP Quality Assurance/Technical Meeting, February 26-28, 2008, Crystal City, VA
- USDA/AMS PDP Quality Assurance/Technical Meeting, March 20-22, 2007, Crystal City,
 VA
- National Archives and Records Administration (NARA), Transfer of Unscheduled Records to Records Storage Center Facilities,

SOP No.: PDP-DATA-08	Page 2 of 8						
Title: Data Storage, Retrieval, and Archival							
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08					

http://www.archives.gov/records_center_program/unscheduled_records_faqs.html (last accessed September 10, 2007)

7 CFR SubchapterE, Subpart C, Section 90.3, Good Laboratory Practices for Commodity Laboratory Analyses

5. **Specific Procedures:**

This SOP represents minimum PDP requirements and is presented as a general guideline. Each participating laboratory shall have written procedures that provide specific details concerning how the procedure has been implemented in that laboratory.

5.1 Data Storage

- **5.1.a** Each participating laboratory shall maintain in its working areas a site-specific record system to suit its particular circumstances, which assures orderly storage and expedient retrieval of data and other records.
- **5.1.b** Physical and environmental conditions of storage shall minimize deterioration of the documents in accordance with the requirements for the time period of their retention and the nature of the documents.
- **5.1.c** Where computers or automated equipment are used for the storage or retrieval of data, the laboratory shall ensure that:
 - **5.1.c.1** Computer software is documented and adequate for use. An example is documentation of Excel spreadsheets and macros. A model set of input data and associated results which have been validated could be constructed. This model could be run periodically to verify correct operation;
 - **5.1.c.2** Procedures are established and implemented for protecting the integrity of data (such procedures shall include but not be limited to integrity of data entry or capture and data storage);

SOP No.: PDP-DATA-08	Page 3 of 8						
Title: Data Storage, Retrieval, and Archival							
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08					

- **5.1.c.3** Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain data integrity;
- **5.1.c.4** Appropriate procedures are established and implemented for the maintenance of security of data including the prevention of unauthorized access or amendment of electronic records.

5.2 Data and Records Retention Periods

- **5.2.a** 25 Years PDP sample data packages, including proficiency testing samples and method validation packages, as defined in SOP PDP-DATA-07
- **5.2.b.** 5 Years Supporting data and records. These include, but are not limited to:
 - Logbooks (e.g. standard preparation, instrument, freezer, temperature, etc.)
 - Chromatograms generated during standards checking (PDP-STD-04)
 - Sample worksheets (e.g., homogenization, extraction, etc.) not specific to individual sample sets
 - · Correspondences and other documents relating to interpretation and evaluation of data
 - Deviation letters
 - Method development studies
 - Staff training records
 - Audit records
 - Control charts
 - Internal laboratory SOPs and instructional documents (current and historical)
 - Sampling documents such as commodity payment records, surplus commodity disposition records, raw Sample Information Form data sheets, etc.
- **5.2.c** The minimum retention at the laboratory for items in 5.2.a shall be two years after transmission of the corresponding data results. Following this minimum on site retention, the sample data packages may be transferred to a Federal Records Center (FRC). Final disposition of these records after the laboratory no longer needs them shall be at a FRC. Special consideration shall be granted for early disposition on a case-by-case basis. All records at the FRC will be disposed of after 25 years from the year of creation.

SOP No.: PDP-DATA-08	Page 4 of 8						
Title: Data Storage, Retrieval, and Archival							
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08					

5.3 Data Archival at the Participating Laboratory

- **5.3.a** An individual(s) shall be identified as responsible for the archives.
- **5.3.b** Access to archived records shall be monitored and controlled. Use of manual or electronic logs are recommended for documenting access.
- **5.3.c** Physical and environmental conditions of storage shall minimize deterioration of the documents in accordance with the requirements for the time period of their retention and the nature of the documents. Locked file cabinets, secured record storage facilities, etc. are acceptable.
- **5.3.d** Documents and records shall be available for inspection by authorized employees or duly designated representative of USDA/AMS.

5.4 Transferring Records to the Federal Records Centers

Note: See Attachment 1, PDP Designated Federal Records Centers.

- **5.4.a** Dispose of all extra copies of records, non-record material (e.g., buckslips, post-it notes, etc.), and metal items (e.g., paperclips, binder clips, etc.) in accordance with individual laboratory security policies. The use of accordion folders is suggested. Binders with non-metal parts (e.g., plastic combs/spirals, 3-ring "Tuffy" mechanisms, etc.) are also acceptable.
- **5.4.b** Sample data packages representing a single calendar year must be transferred separately from other calendar years (i.e., utilizing a different accession number). Within each calendar year, file data packages by month and commodity. Method validation sets and proficiency sample sets may be transferred concurrently with sample data packets from the same calendar year or they may be transferred separately at a later date. If transferred at a later date they shall not be mixed with any type of data set from a different calendar year. Supporting documentation must be transferred separately by time span and subject. *Note: Sample data packages, method validation data, and proficiency test data will be destroyed 25 years after the close of the calendar year in which they were created or completed regardless of when the were transferred to the FRC. The FRC will*

SOP No.: PDP-DATA-08	Page 5 of 8						
Title: Data Storage, Retrieval, and Archival							
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08					

destroy supporting documentation five years after the close of the calendar year in which the latest record was created or completed.

- **5.4.c** All transfers/accessions must be accompanied by an SF-135, Records Transmittal and Receipt (refer to Attachment 2 for form template, Attachment 3 as an example for routine data, Attachment 4 as an example for method validation data, and Attachment 5 as an example for supporting documentation). *Note: An Adobe Acrobat fillable form SF-135 is available on the internet at Federal Records Centers SF 135 Introduction.*
- **5.4.d** Use only FRC boxes when transferring records. Boxes may be obtained by contacting USDA/AMS MPO. Refer to Attachment 6 for illustrated box assembly and packing instructions.
- **5.4.e** When packing records, do not force files into the boxes. Leave approximately one inch of space in each box to permit easy withdrawal of folders. Pack folders upright, with letter size folders facing the front of the container. Do not place folders one on top of another.
- **5.4.f** After the files are boxed, number the cartons sequentially (e.g., 1/10, 2/10, 3/10, etc.) with permanent black marker in the upper right front corner. The box numbers shall correspond to the completed SF-135.
- **5.4.g** Send the completed form to MPO: USDA/AMS/S&T/Monitoring Programs Office 8609 Sudley Rd., Suite 206 Manassas, VA 20110
- **5.4.h** MPO will approve and forward the SF-135 to the FRC for assignment of the accession number. Once the accession number is recorded by MPO, one copy of the SF-135 will be sent back to the transferring laboratory. Upon receipt of the approved SF-135, the accession number shall be placed in the upper left front of the carton. *Note: For method validation data, MPO will also inform the NARA Life Cycle Management Division (NWML) prior to transferring the records to the designated FRC.* All transfers must be forwarded to the FRC within 90 days of the assignment of an accession number. If the FRC does not receive the records during the allotted time period, the accession number becomes null and void. Include the date of disposal on the approved SF-135 on the outside of each box.

SOP No.: PDP-DATA-08	Page 6 of 8							
Title: Data Storage, Retrieval, and Archival								
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08						

- **5.4.i** Place the approved SF-135 and box listing inside the first box of the accession.
- **5.4.j** Close all boxes and seal with filament tape. Ensure that the filament tape does not cover the accession number or the carton number.
- **5.4.k** Ship all boxes to the appropriate designated FRC using the most economical and secure carrier (e.g., Certified US Mail 3rd Class or equivalent). All expenses incurred in transferring records must be charged to the laboratory's PDP allocated funds.

SOP No.: PDP-DATA-08	Page 7 of 8							
Title: Data Storage, Retrieval, and Archival								
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08						

Chris Pappas

Prepared By: Chris Pappas PDP Document Control Officer, Monitoring Programs Office

8609 Sudley Road, Suite 206 Manassas, VA 20110 (703) 330-2300

Gail Parker

6/20/08

Reviewed By: Gail Parker

Presiding Member of PDP Technical Advisory Group Florida Department of Agriculture and Consumer Services

Chemical Residue Laboratory 3125 Conner Boulevard, Building 3 Tallahassee, FL 32399-1650 (850) 410-3057

Diana Haynes

Approved By: Diana Haynes

PDP Technical Director, Monitoring Programs Office

8609 Sudley Road, Suite 206 Manassas, VA 20110

(703) 330-2300

Martha Lamont

Approved By: Martha Lamont

PDP Program Administrative Director, Monitoring Programs Office

8609 Sudley Road, Suite 206

Manassas, VA 20110 (703) 330-2300

> Original Signature Page Maintained by USDA, AMS, Science & Technology, Monitoring Programs Office ELECTRONICALLY REPRODUCED SIGNATURES

SOP No.: PDP-DATA-08	Page 8 of 8							
Title: Data Storage, Retrieval, and Archival								
Revision: 3	Replaces: 04/01/08	Effective: 07/01/08						

Revision 3 May 2008 Monitoring Programs Office

• Added examples of sampling supporting documentation records to Section 5.2.b

Revision 2

- Added data storage requirements for documents necessary to show compliance with PDP requirements to Section 5.1.a.7
- Specified that supporting documentation kept at the laboratory may be discarded after five years in Section 5.2.f
- Added requirement that documents and records be available for inspection by USDA/AMS in Section 5.2.g
- Specified supporting documentation will be retained at FRC for five years in Sections 5.3.b and 5.3.1.1

Revision 1

- Replaced reference to EPA GLP with USDA/AMS GLP reference in Section 4
- Specified binders with non-metal parts are permissible for sending documents to the FRC to Section 5.3.c
- Removed reference to GLP from Section 5.3.c
- Updated the Central Plains Region FRC address in Attachment 1

Original

• Combined all PDP data storage, retrieval, and archival requirements into a single document

USDA/AMS Pesticide Data Program Designated Federal Records Centers

Laboratory	Region	Send to:				
•	_	Name	Address			
California Department of Food and Agriculture	Pacific Region	Federal Records Center	1000 Commodore Drive San Bruno, CA 94066-2350			
Colorado Department of Agriculture	Rocky Mountain Region	Federal Records Center	Bldg. 48, Denver Federal Center West 6 th Avenue and Kipling Street Denver, CO 80225-0307			
Florida Department of Agriculture and Consumer Services	Southeast Region	Federal Records Center	4712 Southpark Blvd. Ellenwood, GA 30294			
Michigan Department of Agriculture	Great Lakes Region	Federal Records Center	7358 South Pulaski Road Chicago, IL 60629-5898			
Minnesota Department of Agriculture	Great Lakes Region	Federal Records Center	7358 South Pulaski Road Chicago, IL 60629-5898			
Montana Department of Agriculture	Rocky Mountain Region	Federal Records Center	Bldg. 48, Denver Federal Center West 6 th Avenue and Kipling Street Denver, CO 80225-0307			
New York Department of Agriculture and Markets	Northeast Region	Federal Records Center	National Archives-Central Plains Region 200 Space Center Drive Lee's Summit, MO 64064-1182			
Ohio Department of Agriculture	Great Lakes Region	Federal Records Center	Federal Records Center – Dayton 3150 Springboro Road Dayton, OH 45439-1883			
Texas Department of Agriculture	Southwest Region	Federal Records Center	1400 John Burgess Drive Fort Worth, TX 76140			
Washington State Department of Agriculture	Pacific Alaska Region	Federal Records Center	6125 Sand Point Way NE Seattle, WA 98115-7999			
USDA, AMS, S&T, National Science Laboratory	Southeast Region	Federal Records Center	4712 Southpark Blvd. Ellenwood, GA 30294			
USDA, GIPSA, TSD, Pesticide Residue Laboratory	Central Plains Region	Federal Records Center	17501 West 98th Street, Room 47-48 Lenexa, KS 66219			

RECORDS TRANSMITTAL AND RECEIPT Ce							proval prior to shipm		of this form to the approecords. See specific instr			PAGE 1	OF	PA	GES
1 7	ГО	(<u>Comple</u> 1228.15		ss for the recor	ds center ser	ving your area	as shown in 36 CFR	5 FRO signed	M (Enter the name and cor receipt of this form will be se	nplete mailing addre	ss of the off	ice retiring	the re	cords.	The
			i	Federal Reco	ords Center	-									
									Γ				٦		
٦	AGENCY TRANSFER AUTHOR- IZATION	₹ .	FERRING AG	BENCY OFFIC	IAL (signatur	e and title)	DATE		'				'		
3	AGENCY CONTACT		FERRING AC	SENCY LIAISC	N OFFICIAL	(Name, office a	and telephone No)								
	RECORDS CENTER RECEIPT	RECOR	DS RECEIVE	ED BY (Signati	ure and Title)		DATE		L						
6	RECEIPT						RECORD	SDAT	Δ					Fold	Lino 🗸
	SSION NU	JMBER		AGENCY			REGORD			DISPOSAL DATE	COMPLE	TED BY R	ECOR	DS CE	NTER
RG	FY	NUMBE R	VOLUME (cu. ft.)	BOX NUMBER S	(w	SERIES DES		RESTRIC-	DISPOSAL AUTHORITY (schedule and item number)		LOCA	TION	SHELF PLAN	CONT.T YPE	AUTO. DISP.
(a)	(b)	(c)	(d)	(e)		(f)		(g)	(h)	(i)	(i.		(k)	<i>(I)</i>	(m)
NSN 7	540-00-634	1 -4093					135-107				Standa	ırd Form 1	35 (Re	av 7-84	5) Face

,	lete the addres		Center for an		ant of ro	cordo. Coo apocifio inetr	uotione on roverse	. 4		DAG	GES
1228.	150.)	ss for the reco	rds center serving your area		5 FRO	cords. See specific instr M (Enter the name and con receipt of this form will be se	nplete mailing addre		g the re		
	i	Federal Rec	ords Center								
		(TYPE	YOUR RECORDS FACI	LITY ADDRESS)		USDA-AMS-S&T Monitoring Programs 8609 Sudley Road, S Manassas, VA 20100	uite 206		1		
2 AGENCY TRANSTER AUTHOR-IZATION	SFERRING AG		CIAL (signature and title)	DATE		manassas. W. 20100					
	SFERRING AC (Laboratory po		ON OFFICIAL (Name, office	and telephone No)							
4 RECORDS RECO	RDS RECEIVE	ED BY (<i>Signat</i>	ure and Title)	DATE		L				5 -1-1	Lino V
6				RECORD	S DATA	1				Loid	Lino W
ACCESSION NUMBER		AGENCY				DISPOSAL		COMPLETED BY F	RECOR	DS CE	NTER
RG FY NUMBER	VOLUME (cu. ft.)	BOX NUMBER S	SERIES DES (with inclusive da		RESTRIC- TION	AUTHORITY (schedule and item number)	DISPOSAL DATE	LOCATION	SHELF PLAN	CONT.T YPE	AUTO. DISP.
(a) (b) (c)	(d)	(e)	(f)		(g)	(h)	(i)	(j)	(k)	(1)	(m)

RG	FY	R	(cu. ft.)	S	(with inclusive dates of records)	RES' TION	(schedule and item number)	DATE	LOCATION	SHEL	CON	AUTC
(a)	(b)	(c)	(d)	(e)	(f)		(h)	(i)	(j)	(k)	<i>(I)</i>	(m)
			20	1-3 4-5 6-9 10-14 15 16-18 19	United States Department of Agriculture Agricultural Marketing Service S&T, Monitoring Programs Office PESTICIDE DATA PROGRAM ROUTINE DATA PACKAGE RECORDS Laboratory (CY 2001) January 2001 February 2001 March 2001 April 2001 May & June 2001 July 2001 August-October 2001 November & December 2001	R						

NSN 7540-00-634-4093 10-14135-107

Standard Form 135 (Rev. 7-85) Facs Prescribed by NARA 36 CFR 1228.152

RECORDS TRANSMITTAL AND RECEIPT Complete and send original and of Contact for appropriate actions											PAGE	OF		0=0		
1	Center for approval prior to snipri										1 1			GES_		
'	1228.150.)							5 FROM (Enter the name and complete mailing address of the office retiring the records. The signed receipt of this form will be sent to this address.)								
			_			oigiiou i	roonpt or and ronn viii bo ot	one to uno address.								
			ŀ		ords Center		USDA-AMS-S&T									
(TYPE YOUR RECORDS FACILITY ADDRESS)								Monitoring Programs	Office							
							8609 Sudley Road, S Manassas, VA 20100				٦					
2	AGENCY	TRANSF	ERRING AG	SENCY OFFIC	SIAL (signature and title)	DATE		Widilassas. VA 20100								
	TRANSFE	R	Chris Donne	a Chamiat												
	AUTHOR-		Chris Pappa	s, Chemist												
3		TRANSF	TRANSFERRING AGENCY LIAISON OFFICIAL (Name, office and telephone No)													
	AGENCY CONTACT	(1	(Laboratory poin		,	,										
			D0 DE0EN/	-D DV (0)	ature and Title) DATE			1								
4	RECORDS CENTER		RECORDS RECEIVED BY (Signature and Title) DATE					L				_				
	RECEIPT															
6	Fold Lino V															
ACCESSION NUM		JMBER		AGENCY				DISPOSAL		COMPLE	TED BY F	RECOR	DS CE	NTER		
RG	FY	NUMBE		BOX NUMBER S	SERIES DESCRIPTION		RESTRIC- TION	AUTHORITY	DISPOSAL			L	<u> </u>	,		
		R			(with inclusive dat		EST	(schedule and item number)	DATE	LOCA	TION	SHELF PLAN	CONT.T YPE	AUTO. DISP.		
		()	(1)	()	(0)			,	<i>(</i> 1)	,	**					
(a)	(b)	(c)	(d)	(e)	(f)		(g)	(h)	(i)	0	j)	(k)	(1)	(m)		
			20		United States Department of Agriculture		R									
		20 United States Department of Agriculture Agricultural Marketing Service S&T, Monitoring Programs Office														
	PESTICIDE DATA PROGRAM															
					METHOD VALIDATION DATA											
		PACKAGE RECORDS Laboratory (CY 2001)				S										
		1-3 January-March 2001, CN														
				4-7	April-November 2001,	MK										

NSN 7540-00-634-4093 10-14135-107

RECORDS TRANSMITTAL AND RECEIPT Complete and send original and one copy of this form to the appropriate Federal Records Center for approval prior to shipment of records. See specific instructions on reverse.										PAGE 1	OF	ΡΔι	GES			
1	ТО	(Complete the address for the records center serving your area as shown in 36 CFR 1228.150.)						5 FROM (Enter the name and complete mailing address of the office retiring the records. The signed receipt of this form will be sent to this address.)								
			Ī	Federal Reco	ords Center YOUR RECORDS FACIL	LITY ADDRESS)	USDA-AMS-S&T Monitoring Programs Office 8609 Sudley Road, Suite 206 Manassas, VA 20100					1				
2	AGENCY TRANSFEF AUTHOR- IZATION	₹	FERRING AC		IAL (signature and title)		'				·					
3	AGENCY CONTACT	(1		GENCY LIAISO oint of contac	ON OFFICIAL (<i>Name, office a</i>											
4	RECORDS CENTER RECEIPT	RECOR	DS RECEIVE	ED BY (Signat	ure and Title)	DATE		L				_				
6 RECORDS DATA											Lino 🕊					
ACCESSION NUMBER AGENCY									COMPLET	ΓED BY F	RECOR	DS CE	NTER			
RG	FY	NUMBE R	VOLUME (cu. ft.)	BOX NUMBER S	SERIES DESCRIPTION (with inclusive dates of records)		AUTHORITY Schedule and item number)	(schedule and item	DISPOSAL DATE	LOCAT	ΓΙΟΝ	SHELF PLAN	CONT.T YPE	AUTO. DISP.		
(a)	(b)	(c)	(d)	(e)	(f)		(g)	(h)	<i>(i)</i>	(j)		(k)	<i>(1)</i>	(m)		
			20	1-3 4-12	United States Department of Agriculture Agricultural Marketing Service S&T, Monitoring Programs Office PESTICIDE DATA PROGRAM SUPPORTING DOCUMENTATION (Laboratory) Single Standards Logbooks, 1/95-12/98 Mixed Standards Logbooks, 7/97-2/99 Semi-annual Program Plans, 1993- 2003											

NSN 7540-00-634-4093 10-14135-107

13-20

Untied States Department of Agriculture Pesticide Data Program Instructions for Assembly and Packaging of Record Boxes

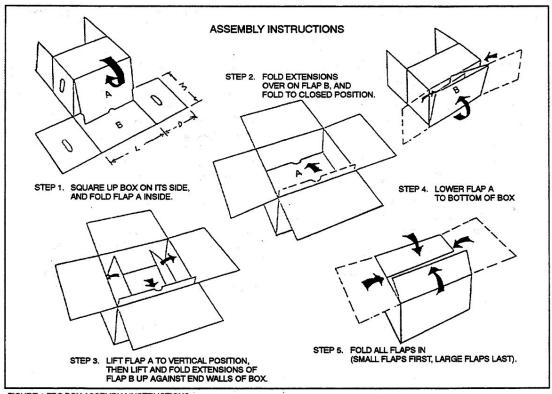


FIGURE 1 FRC BOX ASSEMBLY INSTRUCTIONS

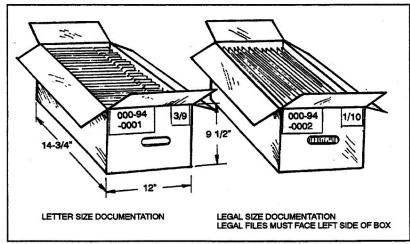


FIGURE 2 FILE PLACEMENT IN BOX AND LOCATION OF BOX IDENTIFICATION